UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *ex rel.* JOSEPH PERRI Plaintiff/Relator, vs. NOVARTIS PHARMACEUTICALS CORPORATION and EXPRESS SCRIPTS, INC. Defendants.	Hon. Kevin McNulty, USDJ Hon. James B. Clark, III, USMJ Civ. No. 15-6547

RELATOR'S CONSOLIDATED BRIEF IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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LEGAL STANDARDS

I. FED. R. CIV. P. 12(B)(6)

The purpose of a Rule 12(b)(6) motion is to test the legal sufficiency of a plaintiff's complaint. *U.S. ex rel. Hunt v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 437 (E.D. Pa. 2004). It is, however, still the defendant's burden to demonstrate that no claim has been presented. *Negron v. Progressive Cas. Ins. Co.*, No. 14-577, 2016 U.S. Dist. LEXIS 24994, *11, 2016 WL 796888, at *4 (D.N.J. Mar. 1, 2016) (citing *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005)). In considering a defendant's motion to dismiss, courts ask "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

The Third Circuit has instructed district courts to conduct a two-part analysis in deciding a motion to dismiss. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, a district court "must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." *Id.* at 210-11 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009)). Second, a district court must determine whether the alleged facts are sufficient to show that a claim is facially plausible. *Fowler*, 578 F.3d at 211 (citing *Iqbal*, 556 U.S. at 678). This plausibility determination, the Third Circuit has cautioned, "does not impose a probability requirement at the pleading stage," but instead "simply calls for enough facts to raise a reasonable expectation

discovery will reveal evidence of the necessary element[s]." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (citing *Twombly*, 550 U.S. at 556); *accord Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012) ("[T]he *Twombly* Court noted that 'a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of the facts alleged is improbable, and that a recovery is very remote and unlikely.'").

II. FED. R. CIV. P. 9(B)

The Third Circuit's particularity standard under Rule 9(b), as applied to False Claims Act ("FCA") complaints, was promulgated in *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153 (3d Cir. 2014). When *Foglia* was decided, the Third Circuit recognized that the circuits were split on how much detail was needed to sustain an FCA claim. *Id.* at 155. Some circuits utilized a heightened standard, requiring "a plaintiff to show 'representative samples' of the alleged fraudulent conduct, specifying the time, place, and content of the acts and the identity of the actors." *Id.* at 155-56 (citations omitted). Other circuits required less, "holding that it is sufficient for a plaintiff to allege 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Id.* at 156 (citations omitted).

The Third Circuit adopted the lesser standard, noting that it had never before required a plaintiff to identify specific false claims at the pleading stage. *Id.* (citing

United States ex Rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 308 (3d Cir. 2011). The Third Circuit also found the heightened standard to be "one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." *Foglia*, 754 F.3d at 156 (quoting *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009). Citing the Solicitor General, the Third Circuit further reasoned that a lesser standard would facilitate "the FCA's effectiveness as a tool to combat fraud against the United States." *Id.*

Ultimately, under Rule 9(b), a court must decide whether a complaint provides adequate notice of the claims. *Argabright v. Rheem Mfg. Co.*, 201 F. Supp. 3d 578, 591 (D.N.J. 2016) (*citing Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir.1984)). This is true in the FCA context as well. *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 258 (3d Cir. 2016). In making this determination, "courts should be sensitive to the fact that application of the Rule prior to discovery may permit sophisticated defrauders to successfully conceal the details of their fraud." *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 284 (3d Cir. 1992), *accord Foglia*, 754 F.3d at 156 (finding that a relaxed standard promotes the FCA's purpose of uncovering fraud).

STATUTORY AND REGULATORY FRAMEWORK

I. THE FALSE CLAIMS ACT

The FCA provides, in relevant part:

> Any person who -- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B) . . . is liable to the United States of America…

31 U.S.C. § 3729(a)(1). The term "knowingly" is defined in the FCA as follows:

> "Knowingly" -- (A) mean that a person, with respect to information-- (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.

31 U.S.C. § 3729(b)(1).

A claim may be "false or fraudulent" in two manners: factually false and legally false. *Wilkins*, 659 F.3d at 305. A claim is factually false when the claimant misrepresents or is caused to misrepresent the goods or services that it provides to the government. *Id.* A claim is legally false when the claimant misrepresents or is caused to misrepresent its compliance with a statutory, regulatory, or contractual requirement. *Id.*[1] Furthermore, compliance with the requirement must be material

[1] *See, e.g.*, *Negron*, 2016 U.S. Dist. LEXIS 24994, at *17, 2016 WL 796888, at *6 (sustaining FCA claims against an auto insurer for causing healthcare providers to bill Medicare as primary, resulting in claims that falsely certified compliance with Medicare secondary payer laws which were a precondition of payment).

to the government's payment decision. *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016).

In sum, to establish a prima facie FCA claim, a relator must allege: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004). For legally false claims, a relator must also demonstrate that a payment term was violated, and that compliance with the payment term was material. *See United States v. Wanaque Convalescent Ctr.*, No. 14-6651, 2017 U.S. Dist. LEXIS 150566, at *6-7, 2017 WL 4122598, at *3 (D.N.J. Sep. 18, 2017) (sustaining legally false claims premised on noncompliance with material secondary payer laws).

II. THE ANTI-KICKBACK STATUTE

The Anti-Kickback Statute ("AKS") prohibits "knowingly and willfully" soliciting or receiving "any remuneration (including any kickback, bribe, or rebate) directly or indirectly… in return for purchasing… or recommending purchasing… any good… for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1)(B). The AKS likewise prohibits "knowingly and willfully" offering or paying "any remuneration (including any kickback, bribe, or rebate) directly or indirectly… to induce… to purchase… or

recommend purchasing… any good… for which payment may be made in whole or in part under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(B).

Congress amended the AKS in 2010 to clarify that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). This amendment was intended to ensure that "all claims resulting from illegal kickbacks are considered false claims for the purpose of a civil action under the [FCA], even when the claims were not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854 (2010).

III. THE DISCOUNT SAFE HARBOR

Federal regulations exempt certain payment practices from AKS liability. *See* 42 CFR 1001.952. These so-called "safe harbors" carve out certain payments from the statute's definition of illegal remuneration. There is a "discount" safe harbor, but it is limited in scope and inapplicable here. 42 C.F.R. § 1001.952(h).

Under this safe harbor, a discount is defined as "a reduction in the amount a buyer (who buys either directly or through… a group purchasing organization) is charged for an item or service based on an arms-length transaction." 42 C.F.R. § 1001.952(h)(5). This definition is exhaustive. 42 C.F.R. § 1001.952(h)(5)(vii) (the term "discount" does not include "other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section"). Specifically excluded from

the discount safe harbor are: "[c]ash payments or cash equivalents"; "[s]upplying one good or service… at a reduced charge to induce the purchase of a different good or service"; "**[a] reduction in price applicable to one payer but not to Medicare,** Medicaid or other Federal health care programs." 42 C.F.R. § 1001.952(h)(5)(i)-(iii) (emphasis added).

ARGUMENT

I. COUNT I SUFFICIENTLY STATED A CLAIM UNDER SECTION 3729(a)(1) OF THE FCA

Relator's allegations, summarized as follows, establish a prima facie claim under 31 U.S.C. § 3729(a)(1):

The parties. Defendant Novartis Pharmaceuticals Corporation ("Novartis") manufactures Gilenya, a prescription drug used to treat multiple sclerosis. (Compl. ¶ 6). Express Scripts, Inc. ("ESI") manages prescription drug formularies for commercial and Medicare Part D health plans. (Compl. ¶ 9). Through its formularies, ESI determines what drugs are covered under a plan and is able to influence how those drugs are utilized by plan members. (Compl. ¶¶ 51-53). By leveraging a drug's formulary placement, ESI is able to obtain discounts from manufacturers like Novartis. (Compl. ¶ 54). From late 2012 and up until his termination in June 2014, Relator Joseph Perri represented Novartis in its commercial *and* Part D negotiations with ESI. (Compl. ¶¶ 76, 78, 113).

The kickbacks. ESI knowingly and willfully solicited/accepted kickbacks in the form of discounts and rebates for its commercial plans by leveraging Gilenya's position on its Part D formulary. (Compl. ¶ 2, 122-23). Conversely, Novartis knowingly and willfully offered/paid commercial discounts in return for access to Part D business. (Compl. ¶ 2, 122-23). Specifically, in 2013, Novartis paid and ESI accepted $7m in commercial rebates in return for Gilenya's continued, unaltered

placement on ESI's Part D formularies. (Compl. ¶¶ 3, 86-88, 123). Even after a cheaper and equally efficacious competitor drug appeared on ESI's formularies in October 2013, Novartis was able to maintain Gilenya's unaltered placement on ESI's Part D formularies through 2014 by providing ESI with steep commercial rebates and protection from price increases. (Compl. ¶ 93-96, 105-06, 122).

The kickbacks were illegal. The foregoing commercial rebates and price protection constitute illegal remuneration under the AKS because they were, in part, intended to induce Gilenya's continued utilization by Medicare recipients. (Compl. ¶ 2, 58, 88, 106, 120). Furthermore, the discount safe harbor is inapplicable because these savings were passed onto commercial plans only, and not to Medicare. (Compl. ¶ 35, 58, 66-67). Defendants' discount arrangement, also known as a swap, violated the AKS. (Compl. ¶ 2).

The kickbacks were the probable result of exploited interests and merged contracting functions. Defendants' AKS violation was facilitated by the high price of Gilenya, which drastically limited ESI's cost allocation for Part D plan members. (Compl. ¶¶ 59-66). Novartis trained its sales representatives, including Relator, to exploit this fact in securing commercial *and* Part D formulary placement in return for commercial discounts only. (Compl. ¶¶ 98-105). Both Defendants also merged their commercial and Part D contracting functions, thus allowing them to swap commercial discounts for Part D business. (Compl ¶ 2, 42-43, 105).

The kickbacks caused false claims. By virtue of the illegal kickbacks, Gilenya maintained its position of ESI's Part D formulary, resulting in false claims to Medicare. (Compl. ¶¶ 120, 124-26). Data from Novartis confirmed that Medicare expended nearly $42 million on Gilenya-related claims for ESI Part D plan members in 2014. (Compl. ¶¶ 116-18, 124-26). That equates to approximately 7,191 claims in 2014, all of which were false under the FCA. (Compl. ¶¶ 116-18, 125).

Thus, the gravamen of Relator's FCA claim is that Defendants violated the AKS by swapping commercial discounts for Part D business, resulting in the submission of false claims to Medicare. As explained *supra*, there are four elements to this type of FCA claim: causation, falsity, knowingly, and materiality. Scienter under the FCA is undisputed (though scienter under the AKS is disputed). It is also uncontested that compliance with the AKS is a material payment term.[2]

Defendants instead attack Count I on falsity grounds, spilling much ink on whether the Complaint alleges an underlying AKS violation.[3] Defendants specifically argue that the Complaint fails to allege scienter under the AKS, that the remuneration was lawful, and that the AKS violations were implausible. Novartis also argues that the Complaint fails to demonstrate causation under the FCA.

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[2] "Compliance with the [Anti-Kickback Statute ("AKS")] is clearly a condition of payment under Parts C and D of Medicare[.]" *Wilkins*, 659 F.3d at 313.

[3] Pursuant to 42 U.S.C. § 1320a-7b(g), falsity is premised on the AKS violation.

A. The complaint establishes an AKS violation, thus satisfying falsity.

1. Intent under the AKS was sufficiently alleged.

The AKS prohibits "knowingly and willfully" offering/paying remuneration for Medicare business. 42 U.S.C. § 1320a-7b(b). While there is no established pleading standard for "knowingly and willfully" in the Third Circuit, courts assess scienter on summary judgment using the "one purpose" test articulated in *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985). Under this test, "the [AKS] has been broadly interpreted to cover any arrangement where ***one*** purpose of the remuneration is to obtain money for the referral of services or to induce future referrals." *United States ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 676 (W.D. Pa. 2014) (emphasis added). "[N]either a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business)." *Id.* at 678 (quoting OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005)).

Courts also scrutinize the business arrangement on summary judgment, and will sustain the AKS claim if "the arrangements or practices… present a significant potential for abuse." *Id.* at 678. Ultimately, however, "whether a business arrangement violates the [AKS] is largely a question of intent, resolution of which is the province of the trier of fact." *Id.* at 679. (citing *United States v. Dollar Bank*

Money Mkt. Account No. 1591768456, 980 F.2d 233, 240 (3d Cir. 1992) (explaining that "a party's mental state is inherently a question of fact"). It is thus generally improper to dismiss an AKS violation at the pleading stage for lack of intent. *Accord* Rule 9(b).

Relator alleged that Novartis paid and ESI accepted remuneration in the form of commercial rebates and commercial price protection in order to secure Gilenya's continued, unaltered placement on ESI's Medicare Part D formularies. (Compl. ¶¶ 3, 66-67, 86-88, 123). Defendants contend that the true purpose of the commercial discounts was to secure preferred commercial placement after a competitor entered the market. (ESI Br. 6). This is a factual dispute not properly resolved on summary judgment, let alone on the pleadings. *See Bartlett*, *Dollar Bank*, *supra*; *see also* Rule 9(b). Defendants also ignore three facets of the Complaint that demonstrate the illegal purpose of the commercial incentives.

First, it is uncontested that each Defendant merged its commercial and Part D contracting functions. (Compl. ¶¶ 2, 42-43, 105). Merged contracting functions has been identified by the OIG and industry experts as likely to produce an illegal swap – the result alleged here.[4] (Compl. ¶¶ 42-43, 66-67). That is why Relator twice

[4] This risk has been explained as follows:

> [I]f Sponsors and manufacturers have not carefully separated Part D and commercial contracting functions, the OIG[]… could stumble upon pricing arrangements in which the manufacturer offers the Sponsor a

requested (and was twice denied) reorganization of his team to separate commercial and Part D responsibilities. (Compl. ¶¶ 78-80). Such inherent risk of abuse should satisfy the scienter threshold at the pleading stage, as it has led other courts to sustain AKS claims on summary judgment. *See Bartlett*, 39 F. Supp. 3d at 678.

Second, Defendants' reaction to Tecfidera, a cheaper equivalent to Gilenya, can only be explained by a swap. (Compl. ¶ 96). Tecfidera's competitive pressure produced steep rebates and price protection for ESI's commercial plans, but no savings for Medicare; in fact, Medicare's costs increased as the price of Gilenya climbed. (Compl. ¶ 93-96, 105-06, 122). Unless one purpose of the commercial incentives was to maintain Part D placement, Gilenya's ability to maintain a position equal to Tecfidera on ESI's Part D formularies in 2013 and 2014 is inexplicable, especially when considering Gilenya's price hike and the lack of any new Part D savings. (Compl. 93-96). The allegations surrounding Tecfidera create a strong inference of illegal intent, as do the marketing practices alleged in the complaint.

> better price on drugs for the Sponsor's commercial plan(s) in return for the Sponsor's Medicare Part D business. Such a "swap" arrangement could raise concerns under the anti-kickback statute. In addition, this type of scheme allows Sponsors to conceal the price concession from Medicare, thereby artificially inflating Part D costs.

ABA Health Law Section, Health Care Fraud and Abuse: Practical Perspectives 815-16 (Linda A. Baumann et al. eds., 2nd ed. 2007).

Finally, Novartis trained its sales representatives to exploit the economics of Medicare Part D when negotiating formulary placement for high-priced drugs like Gilenya. (Compl. ¶¶ 98-104). The Novartis training slides included in the Complaint demonstrate how, at a per annum cost of over $58,903, ESI was responsible for just 16.8% of the total annualized cost of Gilenya under Part D, while Medicare absorbed 70.9% through catastrophic coverage. (Compl. ¶ 100-04). With commercial plans, on the other hand, ESI carried most of the cost burden. (Compl. ¶ 65). ESI was thus motivated to solicit/accept higher commercial discounts at the expense of Medicare (a swap), leading to greater aggregate savings for ESI. (Compl. ¶ 64). And for Novartis, the swap made Gilenya more competitive in the commercial space, and resulted in commercial *and* Part D formulary positions without additional Part D concessions. (Compl. ¶ 105). Novartis exploited these interests to induce the swap. (Compl. ¶ 99). These allegations and the training slides further evince the illegal purpose of the commercial discounts, thus satisfying the "knowingly and willingly" element.

2. The AKS does not require specific intent.

According to both Defendants, scienter is lacking because the Complaint does not allege that either knew its conduct was unlawful. (Novartis Br. 21) ("The Complaint does not identify anyone from Novartis who allegedly 'knew' that the company's conduct was 'unlawful' and nonetheless 'intended' to undertake it.");

(ESI Br. 10) ("The Complaint does not allege that ESI knew it was violating the law.") This is an absurd argument coming from Novartis and ESI. Surely the nation's largest pharmaceutical manufacturer and pharmacy benefit manager know that trading Part D business for commercial discounts is illegal under the AKS. In any event, there is no precedent to support Defendants' ignorance argument.

The AKS itself states that "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation." 42 U.S.C. § 1320a-7b(h). Nor does the FCA require "proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). The Third Circuit has also refused to "carve[] out an exception to the traditional rule that ignorance of the law is no excuse," finding that the AKS is not "highly technical." *United States v. Goldman*, 607 F. App'x 171, 174 (3d Cir. 2015).[5] As discussed *supra*, the Third Circuit employs the "one purpose" test to assess intent/scienter, and Defendants fail that test. Defendants' ignorance argument should be disregarded accordingly.

3. Fair market value is not a relevant consideration.

Novartis contends that courts assess the propriety of a discount based on fair market value, and that a discount does not qualify as remuneration under the AKS unless it is commercially unreasonable. (Novartis Br. 11-13). There is no precedent

[5] Both defendants inappropriately quote a jury instruction that was discussed in dicta in *Goldman*, 607 F. App'x at 174.

for this proposition in the Third Circuit, which is why Novartis relies on opinions from the Western District of Washington and Northern District of Illinois, and why ESI does not make the argument. (Novartis Br. 11).[6] In fact, the argument contradicts Third Circuit law.

As explained *supra*, the propriety of remuneration is dictated by its purpose, not its value.[7] *Greber*, 760 F.2d at 72. And where, as here, the remuneration is intended to induce Medicare referrals, "fair market value" cannot "legitimize [the] payment." *Bartlett*, 39 F. Supp. 3d at 678. As the Third Circuit has repeatedly pointed out, the AKS by its text covers "***any*** remuneration." *Goldman*, 607 Fed. Appx. at 174; *Greber*, 760 F.2d at 71. Novartis's fair market value argument should be disregarded.

Even if fair market value was pertinent to this case, the alleged discount arrangement was commercially unreasonable. As discussed *supra*, the Defendants' reaction to Tecfidera is inexplicable in the absence of an illegal swap. (Compl. ¶ 93-96, 105-06, 122). In the face of such competitive pressure, it was commercially

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[6] Citing *Klaczak ex rel. United States v. Consol. Med. Transp.*, 458 F. Supp. 2d 622 (N.D. Ill. 2006) and *United States v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213 (W.D. Wash. 2011).

[7] Fair market value is relevant in FCA cases premised on the Stark Act, which is not applicable here. *See, e.g., United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602 (W.D. Pa. 2010) (discussing fair market value exceptions to the Stark Act). Certain safe-harbor provisions, not applicable here, also implicate fair market value. *See* 42 CFR 1001.952(a)-(d),(l),(r),(u).

unreasonable for Gilenya to maintain its position of ESI's Part D formularies without additional Part D discounts from Novartis. Accordingly, even if fair market value was relevant, the allegations are adequate.

4. The alleged remuneration is specifically excluded from the discount safe-harbor, further demonstrating its illegality.

If fair market value were relevant to whether a discount qualifies as improper remuneration, then it would be a listed as a consideration under the discount safe-harbor, as it is under other safe-harbor provisions. *Cf.* 42 CFR 1001.952(a)-(d),(l),(r),(u). Furthermore, the discount safe-harbor is explicit in its exclusivity, so any discount beyond its scope – including those that appear commercially reasonable – are unlawful under the AKS. 42 CFR 1001.952(h)(4)(vii) (excluding "[o]ther remuneration, in cash or in kind, not explicitly described…"). Most importantly, the discount safe-harbor specifically excludes from its protection "[a] reduction in price applicable to one payer but not to Medicare…" 42 C.F.R. § 1001.952(h)(5)(iii). Based on this exclusion, the discounts alleged here clearly fall within the scope of the AKS, as they went to ESI's commercial plans only, and not to Medicare. (Compl. ¶ 35, 58, 66-67).

As explained in *United States v. Shaw*, 106 F. Supp. 2d 103, 115 (D. Mass. 2000), the discount safe harbor was meant to "encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs." H.R. Rep. No. 95-393, pt. 2, at 54 (1977). "Thus, one essential

component of this exception is that the federal or state health program share in and benefit from the reduced cost." *Shaw*, 106 F. Supp. 2d at 115. *United States ex rel. Banignan v. Organon USA Inc.*, 883 F. Supp. 2d 277 (D. Mass. 2012) is instructive.

The *Banignan* relators alleged that Organon provided rebates and other incentives to Omnicare to secure a favorably position on Omnicare's Medicaid formulary. *Id.* at 284. Furthermore, Organon marketed its antidepressant "by touting [Omnicare's] 'opportunity to profit' at Medicaid's expense based on the 'spread'" (the difference between the amount Medicaid reimburses Omnicare for a drug and the discounted amount that Omnicare actually pays). *Id.* Omnicare claimed that it was protected under the discount safe-harbor since the rebates were fixed and paid pursuant to a written purchase agreement. *Id.* at 296. The *Banignan* court rejected this argument, holding that the safe-harbor "does not embrace collateral kickbacks or reductions in price which are not passed on to Medicaid [or Medicare]." *Id.* (citing 42 C.F.R. § 1001.952(h)(5)(i)-(iii)).

The remuneration alleged here was equally unlawful, as none of the discounts were passed onto Medicare. All of the elements of an AKS violation thus appear in the Complaint. Defendants' Motions should be denied accordingly.

5. ESI's timing argument is futile.

Citing to a broken hyperlink, ESI contends that its October 2013 threat to exclude Gilenya was implausible because it could not "have readily made changes

to the 2014 formulary." (ESI Br. 9). ESI acknowledges, moreover, that it was empowered to exclude Gilenya from its in 2014. How quickly such an exclusion would go into effect is immaterial, as the threat was sufficient to induce Novartis to pay $7 million in commercial rebates. (Compl. ¶¶ 3, 86-88, 123).

B. Causation was sufficiently alleged.

Pursuant to *Foglia*, a relator need not identify a specific false claim or provide representative samples of false claims. 754 F.3d at 156. A relator may instead provide reliable indicia leading to a strong inference that claims were actually submitted. *Id.* "The Third Circuit has also found that a complaint alleging an AKS-based FCA violation can meet 12(b)(6)'s causation threshold if the complaint alleges a kickback scheme large enough for the defendant to know that at least some of the claims submitted by a third-party would be kickback-tainted." *United States ex rel. Bergman v. Abbot Labs.*, 995 F. Supp. 2d 357 (E.D. Pa. 2014) (citing *Zimmer, Inc.*, 386 F.3d at 235).

In *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 678 (E.D. Pa. 2010), a pharmaceutical manufacturer was accused of bribing physicians to prescribe a drug off-label, and the relator was not required to allege a specific false claim or the identities of doctors or patients. Based on the "wide-ranging marketing scheme," it could be presumed that third parties submitted false claims. *Id.* at 679. The *Underwood* court reasoned that it would be too onerous for

a relator to obtain actual false claims submitted by third parties, such as physicians or pharmacists, at the pleading stage. *Id.* *Underwood* is consistent with *Foglia* and its progeny in this Court.

For example, in *United States ex rel. Rahimi v. Zydus Pharm. (USA), Inc.*, No. 15-6536, 2017 WL 1503986, 2017 U.S. Dist. LEXIS 63401, at *3-5 (D.N.J. Apr. 25, 2017), Zydus was accused of reporting inflated wholesale prices to Medicaid, resulting in large spreads for retail pharmacies that sold Zydus generics to Medicaid insureds.[8] The relators' pharmacies, family-owned stores in New York, realized spreads of up to 424%. *Id.* at 4. The relators concluded that such spreads must have induced pharmacies across the country to submit claims to various Medicaid programs. *Id.* at 13

Zydus sought dismissal under Rule 9 since the complaint failed to "identify the pharmacies involved, the content of or date of any attempt to 'market the spread' or any 'unlawful inducement' to pharmacies, or the drugs at issue." *Id.* at 33. Without such particulars, Zydus argued, the relators could not demonstrate that claims were actually submitted. *Id.* This Court disagreed, holding: "Rule 9(b) does not require such precision." *Id.* (citing *Foglia*, 754 F.3d at 157-58.) Based on the profits margins, there was a strong inference that claims were indeed submitted. *Id.*

[8] As discussed *supra*, the "spread" or margin is the difference between the amount Medicaid reimburses a pharmacy for a drug (typically the average wholesale price) and the amount the pharmacy actually pays for the drug.

Similarly, in *United States ex rel. Penelow v. Johnson & Johnson*, No. 12-7758, 2017 WL 2367050, 2017 U.S. Dist. LEXIS 83335, at *18 (D.N.J. May 31, 2017), a pharmaceutical manufacturer argued that the relators failed to comply with Rule 9. "[T]hey do not identify even one physician who wrote a prescription that was reimbursed by a government payor based on the[] allegedly false statements or when any such prescription was written." *Id.* at 16 (citing the moving brief). The argument failed. Since the kickbacks allegedly resulted in "substantial financial success" for the defendants, this Court was able to infer that claims were actually submitted. *Id.* at 18.

Here, it is alleged that, "[t]hrough their kickback scheme, Defendants caused ESI Part D plan members, along with their pharmacists, to submit false and fraudulent claims to Medicare."[9] Novartis provided the illegal kickbacks to secure Gilenya's position on ESI's Medicare Part D formularies, resulting in Gilenya's continued utilization by Part D plan members. (Compl. ¶ 2, 58, 88, 106, 120). According to the Novartis data cited by Relator, the kickback scheme was a success, yielding 7,191 claims for Gilenya from ESI Part D plan members in 2014. (Compl. ¶¶ 116-18). That equates to nearly $42 million in Medicare expenditure. (Compl.

[9] All of the claims resulting from Defendants' illegal discount arrangement were false and fraudulent under the FCA. 42 U.S.C. § 1320a-7b(g).

¶¶ 116-18, 124-26). Based on the precedent discussed *supra*, these allegations create a strong inference that claims for Gilenya were indeed submitted to Medicare.

According to Novartis, causation is nevertheless lacking because "[t]here are no allegations… about any physician who allegedly prescribed Gilenya, nor any beneficiary of a Part D plan administered by ESI who allegedly received such a prescription, nor the submission of any related claim for Gilenya to the federal government." (Novartis Br. 27). Courts in this Circuit have repeatedly held that such allegations are not required. *See Foglia*, *Bergman*, *Underwood*, *Rehimi*, *Penelow*, *supra*. Consequently, Novartis relies on opinions from outside the Third Circuit. (Novartis Br. 24-28). These non-binding opinions do not warrant discussion, as they apply standards rejected by the Third Circuit.

Novartis also claims that the allegations here are analogous to those discussed in *United States ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, 2017 U.S. Dist. LEXIS 94490 (E.D. Pa. June 19, 2017).[10] (Novartis Br. 25). The *Forney* relator alleged that Medtronic provided a variety of free services to induce physicians to recommend Medtronic devices. *Id.* at 12-14. It was unclear, however, if any physician who received the free services actually submitted a claim to Medicare or Medicaid. *Id.* at 16. That is not a possibility here, as Gilenya's position

[10] Notably, *Forney* proceeded on an amended complaint. *See United States ex rel. Forney v. Medtronic, Inc.*, 2017 WL 2653568, 2018 U.S. Dist. LEXIS 94203 (E.D. Pa., June 4, 2018) (denying summary judgment).

on ESI's Part D formularies definitively resulted in Gilenya's continued utilization by Medicare beneficiaries, yielding nearly $42 million in Medicare expenditure in 2014. (Compl. ¶¶ 116-18, 124-26).

II. RELATOR'S FALSE RECORD CLAIM UNDER 31 U.S.C. 3729 § (a)(1)(B) SHOULD BE SUSTAINED

Section 3729(a)(1)(B) of the FCA imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. Novartis contends that this claim should be dismissed "for the separate reason that the Complaint does not sufficiently allege the existence of a 'false record or statement.'" (Novartis Br. 29). Novartis ignores the false records at the heart of this case – the ESI Part D formularies.

"Novartis unlawfully influenced Part D beneficiary choice" by "providing kickbacks" to "maintain Gilenya's advantageous position on ESI's Part D formularies." (Compl. ¶ 120). Part D plan members "rely on the integrity of ESI's formularies" in deciding what drugs to utilize. (Compl. ¶ 120). The kickbacks tainted the Part D formularies, which itself is a record, resulting in claims to Medicare. (Compl. ¶ 120, 130). Novartis's request to dismiss Count II should be denied. To the extent the formularies must be explicitly identified as the false records, Relator requests leave to amend the Complaint.

III. RELATOR'S CONSPIRACY CLAIM UNDER 31 U.S.C. 3729 § (a)(1)(C) WAS SUFFICIENTLY ALLEGED

A conspiracy claim under the FCA, 31 U.S.C. 3729 § (a)(1)(C), need only satisfy Rule 8. *Rahimi*, 2017 U.S. Dist. LEXIS 63401, at *33-34. Under Rule 8(a), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Specific facts are not required, and the plaintiff need only provide fair notice of the claim. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (describing the "liberal" pleading standard under Rule 8).

To provide fair notice of a conspiracy claim under the FCA, a relator must allege "the general composition of the conspiracy," its "broad objections," and the defendants' roles. This Court has held that allegations regarding a kickback arrangement will support a conspiracy claim. *See United States ex rel. Silver v. Omnicare, Inc.*, No. 11-1326, 2014 WL 4827410, 2014 U.S. Dist. LEXIS 136800, at *15-16 (D.N.J. Sep. 29, 2014). Furthermore, this Court previously rejected the same argument made by Novartis here. *Id.* (rejecting the argument that a complaint must allege an "agreement between PharMerica and its nursing home customers to submit false claims to the government, or an overt act in furtherance of such an agreement.").

Relator alleged that Novartis and ESI engaged in a conspiracy whereby Novartis agreed to provide commercial incentives in return for Medicare Part D business from ESI. (Compl. ¶ 2, 122-23, 132-33). Novartis's objective was to

induce continued utilization of Gilenya by ESI Part D plan members, and ESI's objection was to obtain greater commercial savings. (Compl. ¶¶ 64, 99, 105). Thus, Relator provided adequate notice of the conspiracy's general composition, its broad objections, and Defendants' roles. Novartis's request to dismiss the conspiracy claim should be denied.

IV. RELATOR'S RETALIATION CLAIM UNDER 31 U.S.C. § 3730(h) WAS SUFFICIENTLY ALLEGED

As with conspiracy, a retaliation claim under the FCA, 31 U.S.C. 3730(h), need only satisfy the Rule 8(a) standard. *United States ex rel. Portilla v. Riverview Post Acute Care Ctr.*, No. 12-1842, 2014 WL 1293882, 2014 U.S. Dist. LEXIS 44002, at *17 (D.N.J. Mar. 31, 2014). To plead a retaliation claim under the FCA, 31 U.S.C. 3730(h), a plaintiff must allege that (1) he engaged in protected conduct, and (2) that he was discriminated against because of his protected conduct. *U.S. ex rel. Hefner v. Hackensack University Medical Ctr.*, 495 F.3d 103, 110-11 (3d Cir. 2007). To establish the second element, a plaintiff must demonstrate that "(1) his employer had knowledge he was engaged in protected conduct, and (2) that his employer's retaliation was motivated, at least in part, by the protected conduct." *Id.*

"Determining what activities constitute 'protected conduct' is a fact specific inquiry." *Hutchins v. Wilentz*, 253 F.3d 176, 187 (3d Cir. 2001). "[T]he protected conduct element… does not require the plaintiff to have developed a winning qui

tam action," nor must a plaintiff actually file a qui tam action. *Id.* (internal citations omitted). In order to incentivize self-reporting, "internal reporting and investigation" is generally construed as protected conduct. *Id.*

This Court's opinion in *United States ex rel. Bahsen v. Bos. Sci. Neuromodulation Corp.*, No. 11-1210, 2013 WL 2404816, 2013 U.S. Dist. LEXIS 76612, at *7 (D.N.J. May 31, 2013) is instructive. The *Bahsen* relators alleged that they were trained to use a more profitable diagnostic code when submitting claims to Medicare and Medicaid. *Id.* at 7. The *Bahsen* relators further alleged that they complained about this practice during department meetings, which led to their termination. *Id.* at 7-8. After finding the billing practice to be improper, this Court held that the relators' internal complaints constituted protected conduct. *Id.* at 20 (sustaining the retaliation claims).

Relator's allegations, summarized as follows, provide Novartis with adequate notice of his retaliation claim:

- Novartis provided commercial discounts in return for Gilenya's continued, unaltered placement on ESI's Medicare Part D formularies. (Compl. ¶¶ 2, 122-23). This swap was evinced by the disparity in discount rates provided to ESI commercial plans versus Part D plans. (Compl. ¶¶ 108-110).

- Defendants' swap was facilitated by their merged contracting functions. (Compl ¶¶ 2, 42-43, 105). "Relator twice requested that his team be reorganized so that commercial and Medicare Part D negotiations with ESI for Gilenya would be separated. Relator's supervisor denied both requests." (Compl. ¶ 135).

- "Relator expressed his concerns about the [discount] disparity to his supervisors [at Novartis] and ESI counterpart," and "Relator explained how the existing rebate structure might expose the companies to FCA liability." (Compl. ¶¶ 110, 136).

- After expressing his concerns internally and to ESI, Relator was instructed by his supervisor to "schedule a meeting with ESI for June 18, 2014" to discuss Relator's concerns. (Compl. ¶ 112). Relator's supervisor also instructed Relator to report to Novartis's U.S. Headquarters… on June 17, 2014 to prepare" for the meeting with ESI the following day. (Compl. ¶ 113, 137).

- Relator was terminated by his supervisor when he arrived at headquarters on June 17, 2014. (Compl. 113, 138). Relator was then taken for an exit interview, where Novartis offered Relator a severance package in return for his release of his FCA rights/claims. (Compl. ¶ 138). Relator refused and was escorted from the building. (Compl. ¶ 113).

- Eight days before his termination, Novartis awarded Relator for his outstanding work. (Compl. ¶ 113, 139).

These allegations establish that Relator engaged in protected conduct by complaining to his supervisors about the merged contracting functions and discount disparity, and by warning how these issues exposed Novartis to FCA liability. The dubious nature and timing of the Relator's termination – one day prior to the meeting between Novartis and ESI to discuss Relator's concerns – demonstrates motive and knowledge of the protected conduct, as does Novartis's offer of severance in return for a release of Relator's FCA rights/claims. All of the elements of a retaliation claim were thus alleged, and

Novartis has more than sufficient notice. The retaliation claim should be sustained accordingly.

V. DISMISSAL WITH PREJUDICE WOULD BE IMPROPER

Rule 15 embodies the liberal amendment philosophy of the Federal Rules, providing that a court should "freely give leave" to amend the complaint "when justice so requires." The Third Circuit recognizes this philosophy, requiring district courts to permit curative amendments unless the amendment would be inequitable or futile. *Phillips*, 515 F.3d at 236. Dismissal with prejudice – the relief requested here – is a remedy of last resort. *Id.*

Defendants attack the Complaint as lacking sufficient factual allegations. As discussed *supra*, Defendants seek to impose a pleading standard far higher than the standard articulated in *Foglia*; indeed; one that would require Relator to submit evidence at the pleading stage. If, however, this Court finds that certain facts are missing from the Complaint, then Relator respectfully requests an opportunity to amend its pleading.

CONCLUSION

For the foregoing reasons, Relator respectfully requests an order denying both Motions to Dismiss. In the alternative, Relator requests leave to amend his pleading.

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Dated: August 17, 2018

CERTIFICATION OF SERVICE

I, Jeremy E. Abay, attorney for Relator Joseph Perri, hereby certify that the foregoing Opposition Brief and Proposed Order were electronically filed on August 17, 2017 and are available for viewing and downloading from the ECF system. Service has been made on the parties through their counsel of record via the ECF system.

SACKS WESTON DIAMOND, LLC

s/ Jeremy E. Abay
Jeremy E. Abay

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Date: August 17, 2017